RUTGERS
New Jersey Medical School

Nuclear Medicine, Department of Radiology
Rutgers, The State University of New Jersey
150 Bergen Street, UH C320
Newark, NJ 07302

Nasrin Ghesani, MD
Associate Professor, Radiology & Medicine
Director, Nuclear Medicine
ghesannv@njms.rutgers.edu
p. 973-972-6022
f. 973-972-6954

I. SUBJECT CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Novel Gallium 68 Citrate Imaging in Orthopedic Infections.

Principal Investigator: Nasrin Ghesani, MD

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the Study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?

Dr. Ghesani is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Dr. Ghesani may be reached at:
University Hospital
150 Bergen St, Room H141
Newark, NJ 07101
Phone: (973) 972-1770
Fax: (973) 972-6954

Co-Investigators:
Joseph Benevenia, MD Orthopedics
Francis Patterson, MD Orthopedics
Lisa Dever, MD Infectious Diseases
Michael Sirkin, MD Orthopedics
Basil Hubbi, MD, Radiology
Iman Khodarahmi, Housestaff, Radiology
Yasser Noorelahi, Housestaff, Radiology
Yayone Rivaud, Housestaff, Radiology

The study doctor, Dr. Ghesani, or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?

One of the more serious complications of joint replacement is infection. However, the most common complication is aseptic loosening which is most often caused by wear of the prosthetic component. It is very important to differentiate between infection and non-infectious loosening in order to appropriately care for patients. The current exams and tests used to diagnose these complications are not very sensitive. Therefore, this study is being done to see if Gallium-68 citrate PET/CT can be more useful for diagnosing these complications than the current test, FDG-PET/CT.

PET stands for **P**ositron **E**mission **T**omography and CT stands for **C**omputed **T**omography. PET/CT is a combination of PET images and CT images into one image. Gallium-68 citrate is a special form of the metal gallium that is radioactive. It is injected through a small needle into a vein in the arm. Flourine-flourodeoxyglucose-18 (FDG-18) is a radioactive glucose that is also injected into a vein in the arm.

PET imaging or PET scan takes detailed 3-dimensional pictures of areas of the body. The imaging helps doctors see how the organs and tissues inside your body are functioning. A CT scanner is a special kind of X-ray machine. A computer then processes data into two- and three-dimensional pictures that are displayed on a computer monitor.

When Gallium-68 citrate is used with PET/CT, the scanner can form images and give the doctor information about the size, shape and functional nature of abnormal tissues. The images can be reviewed by a physician to provide information about various medical conditions.

Why have you been asked to take part in this study?

You have been asked to take part in this study because you have had joint replacement and your orthopedic surgeon has also decided that he may need to perform a surgical evaluation to determine if you have a complication from the joint replacement within the next four weeks.

Who may take part in this study? And who may not?

Subjects may take part in this study if they meet ALL the following criteria:

- At least 6 months after joint replacement with complaint of joint pain.
- Radiographic studies compatible with prosthesis failure (i.e. infection or aseptic loosening).
- Pending surgical evaluation and tissue sampling within the next few weeks to differentiate between infection and non-infectious loosening.

Subjects may NOT take part in this study if they meet ANY of the following criteria:

- Pregnant or breast-feeding women.
- Inability to consent.
- Known or suspected hypersensitivity to metals or gallium.
- Joint replacement for any reason other than osteoarthritis.
- Active inflammatory/infectious process at any location other than prosthetic joint.

How long will the study take and how many subjects will participate?

Each subject in the study is expected to participate in two tests, which take about 3 hours each. The tests will occur either on the same day or 24-48 hours apart. There will be a phone call the day after each test and 7 days after the last test. We expect to enroll 17 subjects in the study.

What will you be asked to do if you take part in this research study?

By signing this consent form, you are agreeing to do or allow the following:

PET/CT scan

Prior to the PET/CT scan, an evaluation will be done. During this evaluation a short physical exam will be done including documenting your weight, height, blood pressure, heart rate, and respiratory rate. You will also be asked about any current symptoms you are experiencing. If you are a woman, a urine pregnancy test will be performed.

A PET/CT scan, using Gallium-68 citrate, will be scheduled for you. An intravenous injection of radioactive compound, Gallium-68 will be given to you. You will be asked to void both before and after the intravenous injections. After the injection, there will be a 60-minute waiting period, followed by a PET/CT scan from the top of the head to feet.

The PET/CT scanner is a large machine with a hole in the middle. It looks like a donut with a table in the middle. You will be asked to lie on the table. The table will slide into the machine. You will be asked to remain still during the scan. You will hear buzzing or clicking sounds during the scan. You will need to lie still for about 1-2 hours before coming off of the scanning table.

The size of the opening is 27 to 30 inches. How much space you feel you have around you, will depend on your body size and the scanner. If you feel any nervousness over being in enclosed spaces, let your study doctor know. Each scan will be performed while you lie flat on your back.

Afterwards, you will be undergoing the second scan, FDG PET/CT scan, either on the same day or after 24 – 48 hours. On the day of this scan, you will be asked to fast for 4 hours prior to your test. An intravenous injection of radioactive compound, FDG will be given to you. After the injection there will be a 60-minute waiting period, followed by a PET/CT scan from the top of the head to feet. You will be asked to urinate after the injection of radioactive compound and second time, before starting the scan.

Once you complete your study exams and leave our facility, you will be asked to drink plenty of water and void frequently for remainder of the day.

After each scan, you will have another evaluation. During this evaluation you will be asked about any symptoms you are experiencing. You will also have a short physical exam including documenting your blood pressure, heart rate, and respiratory rate.

Follow-up Phone Calls:

The day after each scan, someone on the research team will call you to ask you some questions about how you are feeling. 7 days after your last scan, someone from the research team will call to see how you are feeling. If you are experiencing any bad effects, we will schedule a follow-up visit with the doctor that referred you to the study.

Review of Medical Chart

We will review basic information in your medical chart. This information will include your current symptoms, medical history, and results of your previous blood and radiology tests. You will be assigned a code number, so that personal identifiers remain confidential.

What are the risks and/or discomforts you might experience if you take part in this study?

This research study involves exposure to radiation emitted by the injected radioactive metal (Gallium-68 citrate), injected radioactive glucose (^{18}fluorine-fluorodeoxyglucose), and the X-rays delivered by the CT scan.

The effective dose is a measure of radiation exposure that is used for calculation of risk. The unit of the effective dose is the millisievert (mSv). You are exposed to radiation from natural sources of radiation all the time. The average person in the United States of America receives an effective dose of about 3 mSv per year from naturally occurring radioactive materials and cosmic radiation from outer space. These natural background radiation doses vary throughout the country. In New Jersey, radon gas is the largest source of natural background radiation. Americans also receive radiation exposures from man-made sources such as medical procedures and consumer products. The USA average exposure from all sources is about 6.2 mSv per year.

From the participation in the study, total effective dose is calculated at 15.1 mSv for women and 14.9 mSv for men.

The risk associated with this level of radiation exposure is too small to be measured and is small when compared with other everyday risks. This is approximately equivalent to a whole body exposure of 1822 days (4.991 years) of exposure to natural background radiation. This use involves minimal risk and is necessary to obtain the research information desired. It is well below the limit of 50 mSv per study allowed by the US Food and Drug Administration for experimental studies in humans. It is also well below the limit of 50 mSv per year that can be received by US radiation workers such as your study doctor, Dr Ghesani.

It is possible, but unlikely, that the injection of Gallium Citrate and FDG will miss the vein. Though there is no subjective data available for such an event, there is a theoretical likelihood of developing skin cancer at the injection site from local radiation.

Theoretically, radiation exposure can damage sperm and eggs. About 2000 mSv is required to cause temporary sterility in humans. The radiation dose to the reproductive organs, testes and ovaries from participation in this study is calculated at approximately 11.8 mSv and 13.3 mSv respectively, about 500 times lower that the dose that can cause permanent sterility. Also, you are not anticipated to be at higher risk of radiation exposure to the egg or sperm that could result in birth defects.

After undergoing PET scan, the subjects should not have close contact with pregnant women, babies and young children for at least 6 hours after their scan.

If you would like more information about radiation exposure, please speak with your study doctor.

Unlikely non-radiation related risks from PET/CT scans include:

- Discomfort from lying still on the enclosed scanning table
- Bruising or bleeding at the site of injection of radiotracer
- Infection at the site of injection
- An allergic type or other adverse reaction to the Gallium citrate or FDG

Are there any benefits for you if you choose to take part in this research study?

There are no direct benefits to your participation in this study. It is hoped that your participation will help us learn how Gallium-68 citrate PET/CT can eventually be used to aid in the management of prosthetic infections.

What are your alternatives if you don't want to take part in this study?

You can simply choose not to take part in this study and to continue follow-up with your orthopedic doctor.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?

You will NOT be responsible for any of the costs involved in this study.

Will you be paid to take part in this study?

You will be given a $50 honorarium for each scan as a token of our appreciation for your participation in this study. You will undergo 2 scans and therefore will be compensated a total of $100.

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. We will do everything we can to protect your privacy. If you join the study, you will be given a code number. The results of the PET scan will be entered into your medical records and will be accessible by authorized health care providers. Collection of information will be limited to that which is pertinent to your participation in this trial. All of the information collected on you and used for this study will be labeled only with your code number. If what is learned from this study is published, your name will not be used.

In addition to members of the study team and your own health care providers, the following people will be allowed to look at parts of your study records:

- The Institutional Review Board (a committee at Rutgers New Jersey Medical School that reviews all research studies)
- The Radiation Safety Committee (a committee at Rutgers New Jersey Medical School that reviews radiation aspects of research studies)
- Officials at the Rutgers New Jersey Medical School.
- Department of Health and Human Resources and the Office for Human Research Protection (regulatory agencies that oversee human research)
- The Food and Drug Administration (FDA)

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen if you are injured during this study?

Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include: radiation exposure, allergic reaction to gallium. In addition, it is possible that during the course of this study, new adverse effects of Gallium-68 citrate that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. If you do not have insurance or your insurance company does not pay the cost, you will be responsible for your medical care. No financial compensation will be provided by the University and no other type of assistance is available from the University.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to:

Principal Investigator:
Nasrin Ghesani, MD
Department of Radiology
Rutgers New Jersey Medical School
50 Bergen Street, UH H 141
Newark, NJ 07103 Phone: (973) 972-1770

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.

Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

Nasrin Ghesani, MD
Department of Radiology
Rutgers New Jersey Medical School
50 Bergen Street, UH H 141
Newark, NJ 07103 Phone: (973) 972-1770

If you have any questions about your rights as a research subject, you can call:

IRB Director: (973)-972-3608 Newark
or
Human Subject Protection Program: 973-972-1149 - Newark

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

- All information in your medical record
- Hospital discharge summaries
- Radiology records or images (MRI, CT, PET scans)
- Medical history or treatment
- Medications
- Consultations
- Laboratory/diagnostic tests or imaging
- Pathology reports, specimen(s) or slide(s)
- Operative reports (about a surgery)
- Emergency Medicine reports

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the study;
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The Institutional Review Board (a committee at Rutgers New Jersey Medical School that reviews all research studies)

- The Radiation Safety Committee (a committee at Rutgers New Jersey Medical School that reviews radiation aspects of research studies)
- Officials at the Rutgers New Jersey Medical School.
- Department of Health and Human Resources and the Office for Human Research Protection (regulatory agencies that oversee human research)
- The Food and Drug Administration (FDA)
- New Jersey Health Foundation

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell her of your decision:

Nasrin Ghesani, MD
Department of Radiology
Rutgers New Jersey Medical School
50 Bergen Street, UH H 141
Newark, NJ 07103 Phone: (973) 972-1770

How long will my permission last?

Authorization for the use and/or disclosure of the Subject's health information will expire on December 31st, 2022.

NOTE: SIGNATURE PAGE FOLLOWS IMMEDIATELY.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____

3. Signature of Consent Process Witness:

I have observed the consent process which included a description of the purposes and procedures of this Study and an opportunity for questions and answers about this Study. I attest that I am not the subject, his/her guardian or authorized representative, or a researcher on this study and can attest that the requirements for informed consent to the medical research have been satisfied.

Printed Name of Witness: _____

Signature of Witness _____ Date _____